IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

PHILIPS NORTH AMERICA LLC	§	
	§	
Plaintiff,	§	
	§	
v.	§	**Case No. 3:22-cv-00147-G**
	§	
IMAGE TECHNOLOGY CONSULTING, LLC; MARSHALL R. SHANNON, IMAGE TECHNOLOGY CONSULTING II, LLC; and AXIOM IMAGING INC.,	§	
	§	
Defendants.	§	

BRIEF IN SUPPORT OF MOTION TO STRIKE EXPERT REPORT AND TESTIMONY OF ALBERTO GUTIERREZ, PHD

Image Technology Consulting, LLC, Marshall R. Shannon, Image Technology Consulting II, LLC, and Axiom Imaging, Inc. (collectively, "Defendants") respectfully move to strike the expert report of Alberto Gutierrez (the "Gutierrez Report") and to exclude the testimony of Alberto Gutierrez, PHD ("Dr. Gutierrez") as inadmissible under Federal Rule of Evidence 702.

INTRODUCTION

1. The entirety of the Gutierrez Report and Dr. Gutierrez's testimony are simply legal opinions interpreting the express language of the Code of Federal Regulations involved in this case, as well as one primary opinion based on Dr. Gutierrez's reading of those regulations, that 21 CFR §§ 820.170 and 820.200 do not impose an obligation on a manufacturer to disclose service information to independent service organizations. Dr. Gutierrez's opinions are improper as nothing more than legal opinions about the meaning of regulations at the core of Defendants' defenses and the claims of Phillips North America, LLC ("Plaintiff"). As Dr. Gutierrez's opinion would

impermissibly invade the province of the Court and the jury, his opinion and his related testimony should be stricken from this trial.

BACKGROUND

2. As part of their defense, Defendants assert that the FDA and the Library of Congress have both expressly held that Defendants are authorized to access the alleged "protected information" that is the subject of Plaintiff's claims. Specifically, Defendants argue that regulations promulgated by the FDA require a manufacturer to "distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device". 21 C.F.R. § 820.170. As an installer and servicer of Plaintiff's devices, Defendants are entitled to receive "directions for ensuring proper installation so that the device will perform as intended after installation" and to ensure patient safety. Id. Both parties argue that their dispute is governed by 21 CFR § 820.170 and/or 21 CFR § 820.220 (collectively, the "Regulations").

21 CFR § 820.170 provides:

> Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device.

In relevant part, 21 CFR § 820.200 provides:

> Where servicing is a specified requirement, each manufacturer shall establish and maintain instructions and procedures for performing and verifying that the servicing meets the specified requirements.

3. Plaintiff retained Dr. Gutierrez "to analyze certain FDA regulations and guidance applicable to manufacturers of medical imaging devices and as related to the matter of *Philips North America LLC v. Image Technology Consulting, LLC; and Marshall R. Shannon*, Case No. 3:22-cv-00147-B, which is pending in the Northern District of Texas, Dallas Division." **APP. 004,**

¶ 16. In support of his assignment, Dr. Gutierrez's prepared a report that contains the following opinion:

> Based on my ***experience reviewing, analyzing, interpreting and applying*** FDA Regulations, it is my opinion that the installation instructions described in 21 CFR 820.170 are limited to the initial installation of the device when sold by the manufacturer and, therefore, would not impose any disclosure obligation on the manufacturer when a used device is subsequently installed or serviced by a third party. It is also my opinion that the servicing instructions and procedures described in 21 CFR 820.200 are limited to those that meet manufacturers own specified requirements. (emphasis added)

APP. 014, ¶ 47.

4. The Regulations require a manufacturer to establish and maintain instructions and procedures for installation, servicing and testing of machines covered by the regulation. However, the Regulations do not expressly allow a manufacturer, such as Plaintiff, to withhold those instructions and procedures from third party service providers such as Defendants. Plaintiff seeks to insert its desired prohibitory language into the Regulations by way of the opinion of Dr. Gutierrez, an alleged expert on the Regulations, who will explain to the trier of fact the meaning of the Regulations based on his "experience reviewing, analyzing, interpreting and applying FDA Regulations." **APP. 014, ¶ 47**. Such opinions are outside the bounds of proper expert opinion allowed under Fed. R. Evi. 702, and therefore, the Gutierrez Report and Dr. Gutierrez's testimony should be stricken from this trial.

LEGAL STANDARD

5. The admissibility of expert reports and testimony is governed by Federal Rule of Evidence 702. Rule 702 was amended to incorporate the principles first articulated by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). Under *Daubert*, expert testimony is admissible only if the proponent of the evidence

demonstrates that: (1) the expert is qualified; (2) the evidence is relevant to the suit; and (3) the evidence is reliable. *Watkins v. Telsmith, Inc.*, 121 F.3d 984, 988-89 (5th Cir. 1997).

ARGUMENT

6. The Gutierrez Report and any testimony to be offered by Dr. Guttierez should be stricken because the heart of both is Dr. Gutierrez's legal opinion as to the meaning of the Regulations. Questions regarding the meaning of a regulation are for the Court, not an expert witness.

7. An expert witness may not deliver legal conclusions on domestic law, for legal principles are outside the witness' area of expertise under Federal Rule of Evidence 702. *See Goodman v. Harris County*, 571 F.3d 388, 399 (5th Cir. 2009). "[A]llowing an expert to give his opinion on the legal conclusions to be drawn from the evidence both invades the Court's province and is irrelevant." *Owen v. Kerr-McGee Corp*., 698 F.2d 236, 240 (5th Cirt. 1983). If an expert witness is allowed to testify to legal questions, each party will simply find its own expert to opine on the law in the light most favorable to its position. *Askanase v. Fatjo*, 130 F.3d 657, 673 (5th Cir. 1997).

8. Dr. Gutierrez role since joining NDA Partners, LLC in 2017 is to interpret the FDA regulations. Dr. Gutierrez admitted to this role during his deposition on August 5, 2024:

> Q Since you've left the FDA in 2017, is it your job description at FDA -- not FDA -- NDA to in interpret the FDA regulations?
>
> A Yes.

APP. 066, p. 102, lines 10-13.

9. Despite Dr. Gutierrez's testimony that he is not providing legal testimony in this lawsuit, the core opinions contained in the Gutierrez Report and his testimony are quintessentially legal. **APP. 001-117**. Dr. Gutierrez testified as follows:

Q Are you providing legal testimony in this lawsuit?

MR. BRENNAN: Object to form.

A I am not.

Q Is it your role to help interpret the regulations in this lawsuit?

MR. BRENNAN: Object to form.

A That's correct.

Q Is it your opinion that the regulations are ambiguous?

MR. BRENNAN: Object to form.

A Not in this area necessarily. I -- I think they're fairly straightforward.

Q And so, you can read the regulation, 21 CFR 820.170 and determine what the obligation is under that regulation.

MR. BRENNAN: Object to form, vague.

A I believe so, yes.

Q Was that a "yes"? I'm sorry.

A Yes.

Q And the same would be true for 21 CFR 820.200?

MR. BRENNAN: Same objection.

A Yes.

APP. 061, p. 84, lines 22-25 – p. 85, lines 1-20.

10. The meaning of regulations is purely a legal question. *Van Winkle v. Rogers*, 2022 U.S. Dist. 165285 at * 13 (W.D. La. Sep. 13, 2022); *see also Kisor v. Wilkie*, 139 S.Ct. 2400, 2432 (2019)(Gorsuch, J. concurring)("Determining the meaning of a…regulation, of course, presents a classic legal question."); *Urso v. United States*, 72 F.3d 59, 60 (7th Cir.1995)("[T]he meaning of a regulation is a question of law for the court, not of fact for the jury."). Dr. Gutierrez does not attempt to hide the fact that he is engaged in legal interpretation as he initially says that his opinion

is based on his "experience reviewing, analyzing, interpreting and applying FDA Regulations." **APP. 014, ¶ 47**.

11. Further, the Gutierrez Report concludes that there is "no basis to assume [the Regulations] compel disclosures of installation or service information to independent service organizations given both the express text of the regulations and by reference to other sections of Title 21." **APP. 014, ¶ 48**. The Gutierrez Report goes on to compare the language in the Regulations with language in other federal regulations to support its conclusion. **APP. 014-016**. Both methods of statutory construction used by Dr. Gutierrez in arriving at his opinion are commonly employed by courts to divine the meaning of an ambiguous law. However, neither party in this case has asserted that the Regulations are ambiguous, and even if either side did make such an assertion, the determination of that ambiguity is a question of law for the Court to determine. Based on the foregoing, allowing Dr. Gutierrez to testify or allowing Plaintiff to submit the Gutierrez Report to the jury would usurp the role of this Court. Therefore, the Guttierez Report should be stricken in its entirety, and Dr. Gutierrez should not be allowed to testify.

PRAYER

WHEREFORE, Defendants pray that the Court strike and exclude the testimony and expert report of Alberto Gutierrez, PHD, and grant such other and further relief as just and equitable.

Respectfully submitted,

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CERTIFICATE OF CONFERENCE

On August 12, 2024, counsel for Defendants conferenced with counsel for Plaintiff regarding the relief sought in the Motion to Strike. Counsel for Plaintiff stated that they are opposed to the Motion.

/s/ Kevin T. Schutte
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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served on all counsel of record on this the 13th day of August 2024, in accordance with the Federal Rules of Civil Procedure.

/s/ Kevin T. Schutte
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